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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,746	10/01/2001	Maurice Zauderer	1821.0060001/EKS/AJK	3613

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/966,746

Applicant(s)

ZAUDERER, MAURICE

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE

3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-7 are pending and under consideration in the present application. Claims 1-7 were rejected in the action mailed on February 25, 2003 (the prior action). Claim 1 was amended in the Response filed May 27, 2003.

### *Claim Rejections - 35 USC § 112*

2. **(Prior Rejection-Withdrawn)** Claim 1 was rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying immunogenic gene products, does not reasonably provide enablement for a method of identifying therapeutic gene products. Applicant's statement that claims 8 and 9 had been cancelled from the application as of the prior action is noted. The claims were rejected as not enabled because determining that a compound is immunogenic does not mean that the compound may be used as a therapeutic. This rejection is withdrawn in view of the amendments to the claims.

3. **(Prior Rejection- Maintained)** Claims 1-7 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims read on methods of screening for potential vaccines for infectious diseases comprising the steps of 1) identifying

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host cell gene products that are up-regulated during infection, and 2) screening said host cell gene products for immunogenicity. These claims are rejected because the applicant has not shown that the claimed method would be effective in identifying potential vaccines for any infectious disease.

The rejection was on the basis that the Applicant has not shown that the claimed method of identifying potential vaccines would in fact identify potential vaccines. As was discussed in pages 6-7 of the prior action, the art surrounding the Applicant's invention gives no indication that the host cell genes that are differentially expressed (up-regulated) during viral infection would be effective vaccine targets against infectious diseases. The application neither identifies any host cell gene products, nor provides any examples of such gene products identified by the claimed method, that have been shown to be potential vaccines. Thus, neither the art, nor the applicants disclosure support the Applicant's assertion that the claimed method would, in fact, be useful "for screening for [host cell] gene products that may be useful as vaccine targets for treating or preventing infectious diseases." Because there is no evidence that any host cell gene whose expression is up-regulated during infection would be an effective vaccine target against the infection, the Applicant is not enabled for the method of identifying such genes.

4. **(Prior Rejection-Withdrawn)** Claims 1-7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been amended to read on methods of screening for potential vaccine targets for infectious diseases comprising a step of identifying genes products that undergo increased expression upon infection, and "screening said

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host cell gene products for immunogenicity.” This claim is rejected for indefiniteness for two reasons. First, it is unclear from the claim what is meant by “immunogenicity.” Secondly, it is unclear how the method steps relate to the potential therapeutics. In view of the amendments to the claims, the rejection is withdrawn.

### ***Conclusion***

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

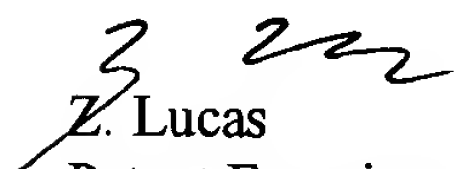
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
July 14, 2003

  
JAMES HOUSEL 7/14/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600